D. PHARMACY SECOND YEAR EXAMINATION, NOVEMBER 2023
EDUCATION REGULATIONS ER 2020

PHARMACY LAW & ETHICS (Question Paper code: 241120233)
(Subject Code: 20261)

Time: Three hours | Maximum marks: 80

Note: 1. Answer all the questions.
2. Draw diagrams wherever necessary

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I. Fill in the blanks 1x5 = 5

1) Schedule X is related to _____
2) The first PCI was constituted by the Central Government in the year _____
3) The full form of NACO is _____
4) Consumer protection act was passé d in the year _____
5) The register for sale of drugs in maintained for a period of ___ years

II. Choose the correct answer 1 x 5 = 5

1) The first edition of Indian Pharmacopoeia was published in the year
(a) 1940 (b) 1950 (c) 1955 (d) 1985

2) The purpose of Phase 3 trials is to
(a) To determine maximum tolerated dose in humans, pharmacodynamic effect and adverse effects
(b) Efficacy and safety of drug in larger number of patients (500 patients)
(c) Determine therapeutic effects and dosage forms
(d) Long time adverse effects

3) Total number of elected members in Pharmacy Council of India is
(a) 4 (b) 8 (c) 9 (d) 6

4) Ethics are the set of moral principles that guides a person's ____
(a) Behaviour (b) Philosophy (c) Profession (d) Religion

5) Pack size of drug is covered under schedule ____
(a) P (b) P1 (c) M (d) N

III. Match the following 1 x 5 = 5

	A	B
1	FSSAI	1971
2	Prevention of Cruelty to animals	2016
3	Clinical Establishments Act	1960
4	Biomedical Waste management	2006
5	Medical termination of Pregnancy act	2010

IV. Write very short answers **1 x 5 = 5**

1) NLEM
2) Schedule N
3) Consumer dispute
4) First Register
5) Patent

V. Write Short Answers on ANY TEN of the following **10 x 3 = 30**

1) Intellectual Property Rights
2) Pharmacists in relation to his job
3) Differentiate between branded and generic drugs
4) Disposal of medical waste from hospital
5) Clinical Trials
6) Classification of Medical devices
7) Functions of DTAB
8) Define the terms adulterated drug, spurious drug and misbranded drug.
9) Prohibited and exempted advertisements
10) Write a note on CDSCO
11) Institutional Animal Ethics Committee

VI. Answer ANY SIX of the following in detail 6x5 = 30

1. Discuss the constitution, composition and functions of State Pharmacy Council.
2. What are the qualifications for appointment of person as a Drugs Inspector? Explain the duties of Drugs Inspector.
3. Explain Drug Control Price Order. Discuss the retail price and ceiling price of scheduled formulations.
4. Write down the contents of Schedule C & C1, Schedule M, Schedule G and Schedule H.
5. Write a note on manufacture in a bonded laboratory
6. Write briefly on Poisons Act, 1919
7. What are the objectives and functions of IAEC and FSSAI?

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